

This guide is for potential applicants to the U.S. Department of Health and Human Services (HHS) Small Business Innovation Research (SBIR) program. The document identifies unique aspects of the HHS SBIR program, describes the nature of its topics, and links readers to additional agency resources. When used in conjunction with MTIP's [Profile of a Good Candidate](#), this guide will help prospective applicants determine quickly whether to pursue funding under the HHS SBIR program and how best to approach a proposal.



THE SBIR/STTR PROGRAMS

The federal Small Business Innovation Research (SBIR) program is a source of early-stage R&D seed capital for small, tech-based U.S. companies. Through 11 different participating agencies, this program offers grants or contracts to support serious R&D and commercialization of technologies of interest both to the government and to the company.

SBIR funding does not have to be matched or repaid by the small business. The award monies can be used to fund most costs associated with the R&D project and up to 7% profit. The company maintains ownership of any new intellectual property (IP), and the government retains certain rights to use the technology. SBIR is a three-phase program. Phase I is to establish the technical and often commercial feasibility of the proposed technology. Phase I awards can be as high as \$225,000, normally for a period of up to nine months. Phase II is to perform more in-depth R&D on the technology, ideally moving it to a prototype. Phase II awards range as high as \$1.5 million for a period of up to two years.

The objective of Phase III is commercialization of the technology. This phase is non-funded though some agencies offer extra assistance in the form commercialization support programs.

In SBIR Phase I, up to 33% of the total budget may go to outside consultants/subcontractors; in Phase II, this figure rises to 50%. In addition, for both Phase I and II, the Principal Investigator (PI) must be greater than 50% employed by the company for the duration of the project.

Each of the 11 participating agencies operates its own version of the SBIR. Within any given agency, the rules and requirements frequently change from one solicitation to the next. Prospective applicants must monitor closely each targeted agency's solicitations.

Overall, agencies report that the chance of winning a Phase I award ranges from is ~7% to ~15%. Well-qualified Montana applicants can substantially improve these odds by working closely with the no-cost services offered by the Montana Technology Innovation Partnership (MTIP). If not currently enrolled for MTIP services, see the information box at the end of this Guide.

THE HHS SBIR PROGRAM

*HHS comprises four major SBIR components—the **National Institutes of Health (NIH)**; the **Centers for Disease Control and Prevention (CDC)**; the **Food & Drug Administration (FDA)**; and the **Administration for Children and Families (ACF)**. Within these four components are 38 separate research institutes, centers, and offices that normally participate in the agency's solicitations. These solicitations are also frequently called "Parent Announcements (PAs)" or "Requests for Application (RFAs)."*

This agency's SBIR program can be challenging because of the broad array of funding opportunities offered through all the different PAs and RFAs. The major opportunity is the SBIR and STTR Omnibus Grant Solicitation of the NIH, CDC, FDA and ACF. This PA is typically released only once each year, usually in late January. Subsequently, proposals to non-AIDS-related topics under this PA may be submitted on April 5th, August 5th, or December 5th, while proposals on AIDS-related topics are typically due May 7, September 7, or the following January 7.

There are funding opportunities outside the Omnibus Solicitation as well. For instance, though most SBIR awards from this agency are grants in response to open, inviting topics, there are also SBIR contract opportunities that call for proposals to highly specific topics. In addition, certain institutes, centers, and offices offer Special Funding SBIR PAs and RFAs targeting specific agency needs, many with larger awards, extended proposal due dates, and longer periods of performance. In these “Special Funding” opportunities, notice that SBIR Phase I is referenced as “R43” and Phase II as “R44.”

IDENTIFYING AN APPROPRIATE TOPIC

<http://www.zyn.com/sbir/scomp.htm> is a great website for tracking and accessing HHS solicitations and their respective topics. In the first box on this page, potential applicants will be able to access the major Omnibus Solicitations for AIDS- and non-AIDS-related research and the numerous Special Funding PAs and RFAs beginning in late January and for the remainder of the year. The PA for contract research opportunities typically opens in August and closes in November. The majority of applicants engaged in medically related R&D are going to be able to identify at least one funding opportunity among all those released by this agency. Contact with MTIP early on can help shorten this process and bring greater clarity to pursuing an SBIR proposal to this agency.

CONTACTING THE AGENCY

Potential applicants who have identified a promising topic are strongly encouraged to communicate with the assigned point-of-contact (POC), for which contact information is provided. The primary purpose of this communication is for the applicant to fully understand what the agency is seeking under a particular topic and how well the applicant’s proposed technology is likely to meet that need.

Though not required, a good way to approach the POC is by sending a 1-2 page write-up on the technology and scheduling a follow-up phone discussion. This write-up should begin with a clear, concise statement of the problem to be addressed and then describe (a) the company, (b) the team and its credentials, (c) the technology being proposed as a solution and an explicit statement of its innovation, (d) the market in terms of what the end product will be, who will buy it and why, an estimate of the number of potential buyers, and how the end product will reach the market, and (e) the competition. Following the phone communication with the POC, the applicant should know whether the technology to be proposed is of interest to the agency.

PREPARING/SUBMITTING THE PROPOSAL

The purpose of the proposal is to provide sufficient information to persuade the review team the proposed technology is a unique and sound solution to the need expressed in the topic. The proposal should be written at a level suitable for publication – that is, with no typos, poor word usage, editorial errors, etc. There are many ways applicants can enhance their chances of success. Here are some keys:

- **Start early.** Many aspects of the proposal can be planned and even drafted well before HHS/NIH ever releases its solicitation by accessing and reviewing prior solicitations at <http://grants.nih.gov/grants/funding/sbir.htm>. (NOTE: The SBIR solicitation is titled SBIR Parent Funding Opportunity Announcement. Other SBIR funding opportunities appear in the same table on this page.) Becoming familiar with the agency’s program requirements early, which includes addressing the many necessary registrations, means the applicant can move much faster once a new solicitation and topics are released.
- **Pre-plan the project.** Before anyone starts writing, applicants should meet with an MTIP counselor to define the objectives to be achieved in each phase of the project. MTIP’s counselor will also make sure the proper proposal format is being used and will provide guidance on responding to each section of the proposal. The project should be vetted against any special considerations identified under the targeted topic area, as well as against the agency’s review criteria. Careful thought should be given to any needed consultants/subcontractors, with the understanding that these individuals should be selected in part to

strengthen the team's credentials. Contact these individuals early to discuss the project, secure their buy-in, begin to collect resumes and biographical data, and co-opt their assistance in preparing the proposal.

- **Read the detailed instructions thoroughly!** All SBIR agencies have specific requirements for font size and style, page limits, marking of confidential information, and other aspects of the proposal. Agencies routinely reject proposals that don't comply with these instructions. One person on the proposal team must be responsible for reading the instructions thoroughly, highlighting all major and minor requirements, and initiating a proposal template. Each solicitation will likely have new requirements. Also, check to see if the agency has posted an instructional webinar on its website.
- **Regardless of the applicant's experience with SBIR, allow time for an MTIP review of the draft proposal.** This review helps ensure the proposal is responsive to the instructions. Even the most experienced applicants have a tendency to get "off point" as they're working through the details of so many sections. The outside review helps catch this drift and ensures the discussion stays focused and "on point." Invariably, good outside reviews identify meaningful ways in which to enhance both the content and the presentation of the proposal. There is strong evidence that MTIP's involvement in the proposal-preparation process significantly improves the chance of funding.
- **Submit early.** In pre-planning the project and proposal, applicants should plan to submit their proposals at least two days prior to the final due date. Early submission avoids the possibility of server overload, which has hampered agencies in the past. It also gives applicants ample time to resolve any problems that arise during the electronic submission process.

READY FOR THE NEXT STEP?

This agency-specific SBIR guide has been prepared by the Montana Technology Innovation Partnership (MTIP) and does not imply endorsement from the U.S. Department of Health and Human Services. A program of the Montana Department of Commerce, MTIP provides free coaching to Montana technology-based companies seeking help in applying to federal and state R&D and commercialization funding programs. For more information, contact the MTIP Program Manager at (406) 841-2749 or visit MTIP's website at www.mtip.mt.gov.

